PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P663PC00	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK 03/00743	International filing date *(day/month/year)* 31.10.2003	Priority date *(day/month/year)* 31.10.2002
International Patent Classification (IPC) or both national classification and IPC G01N33/58		
Applicant CHEMOMETEC A/S et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
12.05.2004	19.01.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Diez Schlereth, D Telephone No. +49 89 2399-7488

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00743

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-43 as originally filed

Claims, Numbers

1-86 as originally filed

Drawings, Sheets

1/12-12/12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-86

   because:

   ☒ the said international application, or the said claims Nos. 1-86 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-86
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-86
Industrial applicability (IA)	Yes:	Claims	
	No:	Claims	---

2. Citations and explanations

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International application No. PCT/DK 03/00743

see separate sheet

While the arguments given by the applicant in his letter of 09.12.04 have been considered, the previously expressed opinion is maintained, for the reasons discussed below.

item III

The scope of claims 1-86 embraces subject-matter concerning diagnostic methods (assessing a quality parameter of a particle present in a liquid material can be interpreted as just detecting a particular analyte in a liquid sample) which may be carried out "in vivo" (the liquid sample may be blood) involving the treatment of living human/animal body by surgery (arranging a volume of liquid material may be interpreted as obtaining a liquid sample). This subject-matter (at present not excluded from the scope of claims 1-86) is considered by this Authority to be covered by the provisions of Rule 67.1 (iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34 (4) (a) (I) PCT).

item V

1.) Reference is made to the following documents:

D1: WO-A-02/008754
D2: WO-A-98/50577

2.) In the light of D1-D2, the subject-matter of claims 1-86 is considered to novel (Art. 33 (2) PCT), but not inventive within the sense of Art. 33 (3) PCT, for the following reasons:

D1 (closest state of the art) discloses a method for detecting/quantifying a parameter of a particle (a cell containing at least one species of "analyte" in an amount of less than 10^6) in a liquid biological sample contained in a well having at least a wall transparent to electromagnetic signals, which comprises labeling the cell to be detected using a specific antigen-antibody binding reaction and detecting the electromagnetic signal generated by the label using an array of detection devices (CCD). The measured signal is processed, whereby the signals measured by one or more detection elements may be corrected for systematic bias, and correlated with the amount of analyte (cells) present in the sample (p. 7, l. 15 to p. 8, l. 34; p. 20, l. 14 to p. 24, l. 24; p. 28, l. 1-10; p. 30, l. 26 to p. 31, l. 31).

The International Examination Authority does not share the view of the applicant given in his letter of 09.12.04 as regards the alleged differences between the method of claim 1 and that disclosed in D1, for the following reasons: the catalyst reagent (an enzyme) used in

D1 for amplification of the analyte signal can be regarded as well as a label reagent (enzymatic labeling is commonly used in biochemistry). The enzyme of D1 is coupled to the analyte (directly) via an antibody that is directed to an epitope of the analyte (first targeting species). It is noted that claim 1 indicates that the first targeting species and the labeling agent can be either directly or indirectly coupled to each other. The attention of the applicant is drawn to the PCT Guidelines for Search and International Preliminary Examination concerning interpretation of the claims (see in particular A5.20 [1-2]).

Therefore, it would appear that the method of claim 1 differs therefrom in that it comprises the additional step of processing th eintensities in order to identify representations of electromagnetic signals from the particles (the cells) as distinct from the representations of electromagnetic signals from background.

This additional step, however, seems to be an obvious procedural alternative which falls within the routine practice in this technical field (see for example D2, p. 5, l. 8-31) and which does not seem to result in any unexpected technical effect.

Dependent claims 2-86 do not seem to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, for the following reasons: the features contained in said claims have been already disclosed in D1 or relate to obvious choices which fall within the routine practice in this technical field.